

## SAT Report for Case # L-19-0033

### General

<b>Report Status:</b>	Complete	<b>Status Date:</b>	05/30/2019
<b>CRSS Date:</b>	12/03/2018	<b>SAT Date:</b>	12/04/2018
		<b>SAT Chair:</b>	Doritza Pagan-Rodriguez
<b>Consolidated PMN?</b>	N		
<b>Consolidated Set:</b>			
<b>Submitter:</b>			
<b>CAS Number:</b>	None		
<b>Ecotox Same As:</b>			
<b>Related Cases:</b>			
<b>Health Related Cases:</b>	(SAME)		
<b>Chemical Name:</b>			
<b>Use:</b>	Intended use:		
<b>Trade name:</b>			
<b>PV</b>			
<b>Max (kg/yr):</b>			
<b>Ecotox Assessor:</b>	Kennedy, Amuel	<b>Fate Assessor:</b>	Lee, WenHsiung
		<b>Health Assessor:</b>	Surapureddi, Sailesh

## Physical Chemical Information

<b>Molecular Weight:</b>		<b>Physical State - Neat:</b>	
<b>Percent 500:</b>		<b>Percent 1000:</b>	
<b>Melting Point (Measured):</b>	71 - 73	<b>Melting Point (est):</b>	
<b>Vapor Pressure:</b>		<b>Vapor Pressure (est):</b>	<0.000001
<b>Water Solubility:</b>		<b>Water Solubility (EST):</b>	<0.000001
<b>Log Kow:</b>		<b>Log P Comment:</b>	
		<b>MPD (EPI):</b>	
		<b>VP (EPI):</b>	
		<b>Water Solubility (EPI):</b>	
		<b>Log Kow (EPI):</b>	

## SAT Concern

<b>Ecotox Rating (1):</b>	1	<b>Ecotox Rating Comment (1):</b>	LVE Parent
<b>Ecotox Rating (2):</b>	2	<b>Ecotox Rating Comment (2):</b>	Degradation product
<b>Health Rating (1):</b>	2	<b>Health Rating Comment (1):</b>	
<b>Health Rating (2):</b>		<b>Health Rating Comment (2):</b>	

## PBT Ratings

Persistence	Bioaccumulation	Toxicity	Comments
1	1	2, HH AND ECO	PMN
3	*	2, HH AND ECO	

Persistence	Bioaccumulation	Toxicity	Comments
			Deg Pdt [REDACTED] [REDACTED], B*(high)

<p><b>Exposure Based Review (Health)?</b></p> <p><b>Exposure Based Review (Ecotox)?</b></p> <p>SAT LUNG, SYST, DEV, AQUATOX (DEG Keywords: PRO)</p>
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<p><b>Fate Assessment L-19-0033</b></p> <p><b>Summary: FATE:</b></p> <p>Solid with MP = 71-73 °C (M)</p> <p>S &lt; 0.001 mg/L at 25 °C (E)</p> <p>VP &lt; 1.0E-6 torr at 25 °C (E)</p> <p>BP = Dec. &gt; 200 °C (M)</p> <p>H &lt; 1.00E-8 (E)</p> <p>POTW removal (%) = 90 via sorption and biodeg; Deg Pdt [REDACTED] 0</p> <p>Time for complete ultimate aerobic biodeg = PMN &gt; mo; Deg Pdt [REDACTED] &gt; mo</p> <p>Sorption to soils/sediments = PMN strong; Deg Pdt [REDACTED] low</p> <p>PBT Potential: PMN P1B1; Deg Pdt [REDACTED] P3B*(high)</p> <p>FATE:</p> <p>Migration to ground water = PMN slow; Deg Pdt [REDACTED] rapid</p> <p>Bioconcentration factor to be put into E-FAST: Deg Pdt [REDACTED] 93</p> <p><b>Removal in WWT/POTW [REDACTED].</b></p> <p><b>(Overall):</b></p>
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Condition	Rating Values w/ Rating Description	Comment
WWT/POTW Sorption:	3;1	PMN; Deg Pdt [REDACTED]

Condition	Rating Values w/ Rating Description	Comment
WWT/POTW Stripping:	3;3	PMN;Deg Pdt [REDACTED]
Biodegradation Removal:	2;4	PMN;Deg Pdt [REDACTED]
Biodegradation Destruction:	3;	PMN;Deg Pdt [REDACTED]
Aerobic Biodeg Ult:	4;4	PMN;Deg Pdt [REDACTED]
Aerobic Biodeg Prim:		
Anaerobic Biodeg Ult:	4;4	PMN;Deg Pdt [REDACTED]
Anaerobic Biodeg Prim:		
Hydrolysis (t1/2 at pH 7,25C) A:		
Hydrolysis (t1/2 at pH 7,25C) B:		
Sorption to Soils/Sediments:	2;4	PMN;Deg Pdt [REDACTED]
Migration to Ground Water:	2;4	PMN;Deg Pdt [REDACTED]
Photolysis A, Direct:		
Photolysis B, Indirect:		
Atmospheric Ox A, OH:		
Atmospheric Ox B, O3:		

## Health Assessment

**Health Summary:** Absorption of the neat substance estimated to be nil all routes (pchem). The LVE of the substance is expected to undergo ester bond hydrolysis in the stomach, releasing a perfluoro compound [REDACTED] which has test data showing systemic and developmental hazards.

The presence of poly/perfluoro moieties

suggests that the LVE substance may induce lung waterproofing.

The  
perfluoro degradation product has analogy to [REDACTED] (see  
same as case [REDACTED]).

The Human Health Form A presents a more  
complete screening profile for this substance including evaluation of its  
uncertainties and available information.

**Routes of Oral,**  
**Exposure: Inhalation**

## Test Data Submitted

**Test Data Journal**

**Submitted:** article submitted: [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

MSDS  
has not HH data or warnings

## Ecotox Assessment

Test organism	Test Type	Test Endpoint	Predicted	Measured	Comments
Fish	96-h	LC50	2.3		Predictions are based on [REDACTED] test data (degradation product)
Daphnid	48-h	LC50	8.3		Predictions are based on [REDACTED] test data (degradation product)
Green Algae	96-h	EC50	3.8		Predictions are based on [REDACTED] test data (degradation product)
Fish	-	Chronic Value	0.23		Predictions are based on [REDACTED] test data (degradation product) with an ACR of 10
Daphnid	-	Chronic Value	3.1		Predictions are based on [REDACTED] test data (degradation product)
Green Algae	-	Chronic Value	1.7		Predictions are based on [REDACTED] test data (degradation product)

Factors	Most Sensitive Endpoint	Assessment Factor	CoC	Comment
Acute Aquatic:	2300	5	460	Fish acute test data on [REDACTED] (Degradation product)
Chronic Aquatic:	230	10	23	Fish acute test data on [REDACTED] (Degradation product) with an ACR of 10

**Ecotox Route of Exposure?** All releases to water

Factors	Values	Comments
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Factors	Values	Comments
SARs:		
SAR Class:		
TSCA NCC Category?	None	

## Recommended Testing

### Ecotox Value Comments

Predictions are based on [REDACTED] test data (degradation product); MW [REDACTED] Log Kow = 13.35 (P); [REDACTED] with a MP = 71-73C (M); S = 2.6E-10 mg/L (P); effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150 mg/L as CaCO<sub>3</sub>; and TOC <2.0 mg/L.

#### Fish Ecotoxicity Test:

[REDACTED] conducted a 96-hour acute toxicity test in rainbow trout (*Oncorhynchus mykiss*) with the analog substance, [REDACTED] (purity not specified), under semi-static conditions with daily renewal. This study followed OECD test guideline No. 203 (1992) referenced as Method C.1 of Commission Directive 92/69/EEC. Following a preliminary range-finding test, single replicates of seven *O. mykiss* were exposed to a dilution water control (dechlorinated, softened tap water) or the analog substance at nominal concentrations of 1.3, 2.3, 4.2, 7.3 and 13 (saturated solution) mg/L. Corresponding time-weighted mean measured test concentrations were 0.276, 0.486, 1.02, 1.83 and 3.27 mg/L, as determined by GC-FID analysis (LOQ = 0.033 mg/L). Due to the low aqueous solubility and the high purity (not specified) of the test material, the test concentrations used in the definitive test were prepared by diluting a saturated solution prepared from initial test material dispersions at a concentration of 50 mg/L. To prepare the test solutions, an amount of test material (1150 mg) was dispersed in 22.5 liters of dechlorinated tap water with the aid of propeller stirring at approximately 1500 rpm at 14°C for a period of 24 hours. After 24 hours, the stirring was stopped and the undissolved test material was removed by filtration (0.2 µm Gelman SuporCap filter, first approximate 1 liter discarded in order to pre-condition the filter) to give a saturated solution with a nominal concentration of 13 mg/L. This nominal 13 mg/L test concentration was prepared in duplicate or triplicate to ensure a sufficient volume was available for testing and dilution. Aliquots (2.5, 4.42, 8.08 and 14 liters) of this nominal 13 mg/L test concentration were each separately dispersed into a final volume of 25 liters of dechlorinated tap water and stirred using a flat-bladed mixer for approximately 1 minute to give the remainder of the test series of nominal test concentrations of 1.3, 2.3, 4.2 and 7.3 mg/L. The test vessels filled with minimal headspace and then sealed to reduce volatilization. The test material

preparations were observed to be clear colorless solutions throughout the duration of the test. Over the course of the study, temperature ranged from 13.2-14.0°C, pH ranged from 7.3-8.4 and dissolved oxygen ranged from 7.9-10.2 mg/L. Dilution water hardness was ~100 mg CaCO<sub>3</sub>/L. A loading rate of 0.36 g fish/L was reported. Sub-lethal effects of exposure were observed at nominal test concentrations of 4.2 mg/L and above. These responses were swimming at the surface, swimming at the bottom, increased pigmentation, swimming at the surface with increased pigmentation, swimming at the bottom with increased pigmentation, and the presence of moribund fish. After 29 hours of exposure, seven out of seven fish were observed to be moribund at the nominal concentration of 13 mg/L and were killed due to the approach of the substantial severity limit. These fish were classified as mortalities for the 48-hour time point. The cumulative percent mortality at nominal test concentrations of 0 (control), 1.3, 2.3, 4.2, 7.3 and 13 mg/L was 0, 0, 0, 0, 14 and 100%, respectively. Based on time-weighted mean measured test concentrations, the 96-hour LC<sub>50</sub> was 2.3 mg/L.

96-hour LC<sub>50</sub> = 2.3 mg/L

#### Daphnid Ecotoxicity Test:

██████████ conducted a 48-hour acute immobilization test in *Daphnia magna* with the analog substance, ██████████ (purity not specified), under static conditions. This study followed OECD test guideline No. 202 (1984) referenced as Method C.2 of Commission Directive 92/69/EEC. Following a preliminary range-finding test, two replicates of ten *D. magna* each were exposed to a dilution water control (reconstituted water) or the analog substance at nominal concentrations of 0.14, 0.25, 0.45, 0.78, 1.4, 2.5, 4.5, 7.8 and 14 (saturated solution) mg/L. GC-FID analysis of the test solutions at 0 and 48 hours showed measured test concentrations to be 76-121% of nominal (LOQ = 0.0067 mg/L); therefore, results are based on nominal test concentrations only. Due to the low aqueous solubility and the high purity (not specified) of the test material, the test concentrations used in the definitive test were prepared by diluting a saturated solution prepared from an initial test material dispersion at a concentration of 50 mg/L. To prepare the test solutions, an amount of test material (550 mg) was dispersed in 11 liters of reconstituted water with the aid of propeller stirring at approximately 1500 rpm for a period of 24 hours. After 24 hours, the stirring was stopped and the undissolved test material was removed by filtration (0.2 µm Gelman SuporCap filter, first approximate 1 liter discarded in order to pre-condition the filter) to give a saturated solution with a nominal concentration of 14 mg/L. Aliquots (10, 18, 32, 56, 100, 179, 321 and 557 mL) of the 14 mg/L test concentration were each separately dispersed in a final volume of 1 liter of reconstituted water to give the remainder of the test series of nominal test concentrations of 0.14, 0.25, 0.45, 0.78, 1.4, 2.5, 4.5 and 7.8 mg/L. The test flasks were completely filled with minimal headspace and then stoppered to reduce volatilization. The test material preparations were observed to be clear colorless solutions throughout the duration of the test.

Over the course of the study, temperature ranged from 21.1-21.5°C, pH ranged from 7.9-8.0 and dissolved oxygen ranged from 8.2-8.3 mg/L. The dilution water had an approximate theoretical total hardness of 250 mg CaCO<sub>3</sub>/L. A loading rate of 40 daphnids/L was calculated. Cumulative percent immobilization at test concentrations of 0 (control), 0.14, 0.25, 0.45, 0.78, 1.4, 2.5, 4.5, 7.8, and 14 mg/L was 0, 0, 0, 0, 0, 0, 0, 10, 25 and 100%, respectively. Based on analytically confirmed nominal concentrations, the 48-hour EC<sub>50</sub> was 8.3 mg/L.

48-hour EC<sub>50</sub> = 8.3 mg/L

#### Algal Ecotoxicity Test:

██████████ conducted a 72-hour growth inhibition test in green algae (*Scenedesmus subspicatus*) with the analog substance, ██████████ (purity not specified), under static conditions. This study followed OECD test guideline No. 201 (1984), referenced as Method C.3 of Commission Directive 92/69/EEC. Following a preliminary range-finding test, three replicates of *S. subspicatus* (~10,000 cells/mL) were exposed to a culture medium control or the analog substance at nominal concentrations of 0.81, 1.6, 3.3, 6.5 and 13 (saturated solution) mg/L. Corresponding mean measured test concentrations were 1.3, 2.3, 3.1, 6.7 and 13 mg/L, as determined by GC-FID analysis (LOQ = 0.017 mg/L). The algae were illuminated with a light intensity of approximately 7000 lux with constant shaking. Due to the low aqueous solubility and the high purity (not specified) of the test material, the test concentrations used in the definitive test were prepared by diluting a saturated solution prepared from an initial test material dispersion at a concentration of 50 mg/L. To prepare the test solutions, an amount of test material (550 mg) was dispersed in 11 liters of culture medium with the aid of propeller stirring at approximately 1500 rpm for a period of 24 hours. After 24 hours, the stirring was stopped and the undissolved test material was removed by filtration (0.2 µm Gelman Acrocap filter, first approximate 1 liter discarded in order to pre-condition the filter) to give a saturated solution with a nominal concentration of 13 mg/L. A series of dilutions was made from this saturated solution to give further stock solutions at nominal concentrations of 0.81, 1.6, 3.3 and 6.5 mg/L. An aliquot (2 liters) of each of the stock solutions was separately inoculated with algal suspension (10 mL) to give the mean measured test concentrations of 1.3, 2.3, 3.1, 6.7 and 13 mg/L. The test flasks were completely filled with minimal headspace and then stoppered to reduce volatilization. At the start of the test, all control and test cultures were observed to be clear colorless solutions. After the 72-hour test period, all test cultures for the control and measured concentrations of 1.3, 2.3 and 3.1 mg/L were observed to be bright green dispersions. The 6.7 mg/L test cultures were observed to be green dispersions whilst the 13 mg/L test cultures were observed to be very pale green dispersions. Over the course of testing, temperature was maintained at 24±1°C and pH ranged from 7.9-9.9. The mean cell density of control cultures increased by a factor of ~66 within 72 hours. At the 72 hour microscopic inspection, there

were no abnormalities detected in the control or test cultures at measured concentrations of 1.3, 2.3, 3.1 and 6.7 mg/L, however, few intact cells were observed to be present in the test cultures at 13 mg/L. Based on mean measured test concentrations, the 72-hour EC50 values were 3.8 and 7.8 mg/L for biomass and growth rate, respectively. The 72-hour NOEC and LOEC were 1.3 and 2.3 mg/L, respectively. The calculated ChV was 1.7 mg/L.

72-hour EC50 (biomass) = 3.8

mg/L

72-hour EC50 (growth rate) = 7.8 mg/L

72-hour NOEC = 1.3

mg/L

72-hour LOEC = 2.3 mg/L

Algal ChV = 1.7 mg/L

The additional  
information is from the ECHA  
website

<https://echa.europa.eu/registration-dossier/-/registered-dossier> [REDACTED]

Daphnid

Chronic Ecotoxicity Test:

21-d NOEC = 2.16 mg/L

21-d LOEC = 4.46

mg/L

21-d MATC = 3.10 mg/L

## **Ecotox Factors Comments**

Environmental

Hazard: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA determined environmental hazard for this new chemical substance based on [REDACTED] test data (degradation product).

Acute toxicity values estimated for fish, aquatic invertebrates, and algae are 2.3 mg/L, 8.3 mg/L, and 3.8 mg/L, respectively. Chronic toxicity values estimated for fish, aquatic invertebrates, and algae are 0.23 mg/L (ACR of 10), 3.1 mg/L, and 1.7 mg/L, respectively. These toxicity values indicate that the new chemical substance is expected to have high environmental hazard.

Application of assessment factors of 5 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 0.46 mg/L (460 ppb) and 0.023 mg/L (23 ppb), respectively.

Environmental

Risk: Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Risks

to the environment were not identified due to releases to water that did not exceed the acute COC or the chronic COC.